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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/885,537	06/21/2001	Myron Spector	1194-176	2633

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EXAMINER
GUCKER, STEPHEN

ART UNIT	PAPER NUMBER
1647	12

DATE MAILED: 04/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/885,537	Spector et al.
Examiner	**Group Art Unit**
Stephen Gucker	1647

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Peri d for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☑ Responsive to communication(s) filed on 2/27/03.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle,* 1935 C.D. 1 1; 453 O.G. 213.

Disp sition of Claims

☑ Claim(s) 1 - 22 is/are pending in the application.

Of the above claim(s)____ is/are withdrawn from consideration.

☐ Claim(s)____ is/are allowed.

☑ Claim(s) 1 - 22 is/are rejected.

☐ Claim(s)____ is/are objected to.

☐ Claim(s)____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Pri rity under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number)____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received:____.

Attachment(s)

☑ Information Disclosure Statement(s), PTO-1449, Pap r No(s). 10+11

☐ Interview Summary, PTO-413

☑ Notice of Reference(s) Cit d, PTO-892

☐ Notice of Informal Patent Application, PTO-152

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Other____

Office Action Summary

Response to Amendment

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Any objections or rejections made in a previous Office Action that are not herein reinstated have been withdrawn. Upon extensive reconsideration and additional searching, the Examiner has combined some of the prior art of record with new prior art to arrive at the instant rejections. The Examiner sincerely regrets indicating claim 18 as being potentially allowable in the previous Office Action.

3. Claims 1-7, 9-15, 19 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Geistlich et al. (US 5,837,278; "'278") in view of Shimizu (US 6,090,117) and further in view of the abstracts of Hentz et al. and Rosen et al.

The '278 patent discloses a single sheet of a resorbable sidewall material consisting essentially of a single layer collagen sheet material having a compact, smooth outer barrier surface so as to inhibit cell adhesion thereon and act as a barrier to prevent passage of cells therethrough, this sheet material further having a fibrous inner surface opposite the smooth barrier surface (column 1, line 51 to column 2, line 6) derived from collagen membrane peritoneal tissue (column 2, lines 52-60). This single layer collagen sheet material is identified as Bio-Gide ® by the instant specification (page 3, lines 6-11), thereby meeting the limitations of the instant claims. The '278 patent does not disclose a nerve regeneration tube for connecting

nerve ends having an inner diameter of about 0.5-5mm and a length of about 10-100mm formed from the single collagen sheet of the '278 patent, or a filling material comprised of a mixture of Type I and Type IV collagen, or collagen fibers having a substantially longitudinal orientation with respect to said tube, or a filling material including laminin as a nerve growth stimulant. Shimizu discloses a nerve regeneration tube comprising of at least three sheets of collagen (column 6, line 48 to column 7, line 50, and as indicated by Applicant's response filed 2/27/03, Paper No. 10, Amendment B, page 4) but which is also about 1-8mm in inner diameter with a length about 28-35mm, but can differ according to the length of the severed portion of the nerve and the thickness of the nerve (column 7, lines 19-31; see also a 10mm long tube in Comparative Example 4), thereby meeting the limitations of the instant claims. Shimizu also teaches filling materials for a nerve regeneration tube comprising laminin and Type IV collagen (column 8, lines 40-55) and collagen Type I solution or fibers having a substantially longitudinal orientation with respect to said tube (column 7, line 55 to column 8, line 13; column 8, line 65 to column 9, line 48). Shimizu does not explicitly disclose a reasonable expectation of success of making a collagen nerve regeneration tube out of a collagen sheet of membrane. Both Hentz et al. and Rosen et al. teach in their abstracts the feasibility and likelihood of success of making collagen tubes out of collagen sheets or membranes. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the single sheet collagen material of the '278 patent to make a nerve regeneration tube out of collagen as taught by Shimizu because Shimizu employs at least three sheets of collagen to produce his nerve regeneration tube and by using a single sheet

of collagen with the attractive features (one side smooth and inhibits cell permeation, the other side fibrous to promote biological regrowth) taught by the '278 patent, a simpler nerve regeneration tube can be produced that uses less material (single sheet as opposed to at least three sheets of collagen), is quicker and easier to produce, and would have the further advantage of economic savings due to lowered costs of production by reducing the need for at least three sheets of collagen to a single sheet of collagen. The combined references also establish a *prima facie* case of obviousness because the collagen material of the '278 patent has desirable features such as a smooth surface to inhibit cell adhesion on the outside with a fibrous surface to support cells on the inside and simply forming a tube out of this two-sided collagen material is *prima facie* obvious given that collagen nerve regeneration tubes were in use at least as way back as the 1980s, and the '278 patent collagen material is used as a single sheet to make a collagen nerve regeneration tube as opposed to at least three sheets of collagen which are used in the prior art of record. Finally, the advantageous characteristics of the two-sided collagen material of the '278 patent would suggest to and motivate the ordinary artisan to fashion the collagen material into a tube with a smooth outside and fibrous inside in order to promote axonal regeneration in the interior of the tube as indicated by Shimizu (column 7, line 55 to column 8, line 13; column 8, line 40 to column 9, line 63).

4. Claims 16-18 and 20-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Geistlich et al. (US 5,837,278; "'278") in view of Shimizu (US 6,090,117) and further in view of the abstracts of Hentz et al. and Rosen et al. as applied above and further in view of Stensaas et

al. (US 4,778,467, "Stensaas"). None of Geistlich or Shimizu or Hentz et al. or Rosen et al. explicitly teach methods of forming tubes from collagen sheets, although Shimizu does teach a collagen nerve regeneration tube and Hentz et al. and Rosen et al. do describe making tubes from collagen sheets. Stensaas teaches methods of forming tubes for nerve regeneration (Figures 1 and 3A-3B, column 10, line 3 to column 11, line 5) with or without silicone rubber adhesive that meet the limitations of the instant claims (also see column 9, lines 1-16 and column 16, lines 54-66 (Figures 7A-7B) for overlapping edges). It would have been obvious to one of ordinary skill in the art at the time of the invention to employ the teachings of Stensaas to make various kinds of tubing (opposed edges, overlapping edges, etc.) out of a collagen sheet material because the other references, while teaching the desirability of doing so, lack explicit descriptions and drawings as to how to accomplish the actual construction of various types of tubes for nerve regeneration, which Stensaas does teach. The ordinary artisan, searching for information to fabricate nerve regeneration tubes, would find the teachings of Stensaas and find it *prima facie* obvious to use his disclosure in combination with the other references because Stensaas supplies the explicit teachings that the other references lack concerning nerve regeneration tube construction.

5. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Geistlich et al. (US 5,837,278; "'278") in view of Shimizu (US 6,090,117) and further in view of the abstracts of Hentz et al. and Rosen et al. as applied above and further in view of Humes (US 5,429,938). None of Geistlich or Shimizu or Hentz et al. or Rosen et al. teach a mixture of Type I and Type

IV collagen in a ratio of about 1:1 for supporting biological activity. Humes does teach the use of Type I and Type IV collagen in about 1:1 ratios to support biological activity (column 3, lines 65-66). It would have been obvious to one of ordinary skill in the art at the time of the invention to employ Humes' ratio of about 1:1 of Type I and Type IV collagen because the other references do not qualitatively teach specific amounts between Type I and Type IV collagen and the artisan would be motivated to look to the Humes reference to supply this missing information if said artisan was actually going to reduce to practice a combination of Type I and Type IV collagen because such information would be required during fabrication.

6. No claim is allowed.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Gucker whose telephone number is (703) 308-6571. The examiner can normally be reached on Monday to Friday from 0930 to 1800. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623. The fax phone number for this Group is currently (703) 308-4242, but Applicant should confirm this by phoning the Examiner before faxing.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

SG

Stephen Gucker

April 5, 2003

Gary L. Kunz

GARY KUNZ
SUPERVISORY PATENT EXAMINER
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